DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 1, 2015

Silk Road Medical, Inc.
Ric Ruedy
Vice President, RA/CA/QA
735 North Pastoria Ave.
Sunnyvale, CA 94085

Re: K143459
Trade/Device Name: Silk Road Access Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: February 13, 2015
Received: February 18, 2015

Dear Mr. Ruedy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K143459

Device Name: Silk Road® Access Catheter

Indications for Use:

The Silk Road® Access Catheter is indicated for the introduction of interventional devices into the peripheral vasculature.

Prescription Use ___X___ Or Over-The-Counter Use _____

(per 21 CFR 801.109)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

I. SUBMITTER

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Date Prepared:
March 17, 2015

II. DEVICE

Name of the Device: Silk Road® Access Catheter
Common or Usual Name: Percutaneous Catheter
Classification Name: Percutaneous Catheter (21 CFR§ 870.1250)
Regulatory Class: Class II
Product Code: DQY

III. PREDICATE

Silk Road Medical, Inc. Silk Road® Access Catheter (K130649)
This predicate has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The Silk Road Access Catheter is a sterile, non-pyrogenic, single-use access catheter indicated for introduction of interventional devices into the peripheral vasculature. The Silk Road Access Catheter is a single-lumen, coil-reinforced shaft, variable stiffness catheter in a range of diameters and working lengths to accommodate target anatomy. All sizes contain a radiopaque marker on the distal end and a catheter hub on the proximal end. The catheter shaft has a hydrophilic coating on its distal portion to reduce friction during use. The catheter is offered with a dilator. The Silk Road Access Catheter is a limited duration (<24 hours), external-communicating device, contacting circulating blood.

V. INDICATIONS FOR USE

The Silk Road® Access Catheter is indicated for the introduction of interventional devices into the peripheral vasculature.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Subject Device and Predicate Device are identical with respect to the following:

- Sterile, non-pyrogenic disposable, single-use devices
- Intended for use to provide an access conduit for the introduction of interventional devices
- Indicated for use in introduction of interventional devices into the peripheral vasculature
- Target anatomical site is the peripheral vasculature
- Single-lumen, coil-reinforced shaft, variable stiffness catheter in a range of diameters and working lengths to accommodate target anatomy. All sizes contain a radiopaque marker on the distal end and a catheter hub on the proximal end. The catheter shaft has a hydrophilic coating on its distal portion to reduce friction during use. The catheter is offered with a dilator.

The following technological differences exist between the Subject Device and Predicate Device:

- Use of additional polymer in catheter shaft
- Use of different material for catheter shaft support
- Use of tensile reinforcement for catheter shaft

The technological characteristics and principles of operation of the Silk Road Access Catheter are substantially equivalent to the named Predicate Device.

VII. PERFORMANCE DATA

The following performance testing was conducted on the Silk Road Access Catheter to support a determination of substantial equivalence to the Predicate Device.

Biocompatibility

The biocompatibility evaluation for the Silk Road Access Catheter was conducted in accordance with the FDA Blue Book Memorandum #G-95-1 "Use of International Standard ISO 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices- Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The battery of tests included the following tests:

- Cytotoxicity: MEM Elution L-929 ISO/USP
- Sensitization: Guinea Pig Maximization Sensitization Test
- Irritation: ISO Intracutaneous Reactivity Test
- Systemic Toxicity: ISO Acute Systemic Injection
- Hemocompatibility:
    - Four Hour Thromboresistance Evaluation in Dogs
    - Complement Activation C3a and SC5b-9
    - Platelet and Leukocyte Count
    - Partial Thromboplastin Time
    - Hemolysis
- Genotoxicity:
    - Bacterial Mutagenicity Test- Ames Assay
    - *in vitro* Mouse Lymphoma Assay
    - *in vivo* Mouse Micronucleus Assay
- Pyrogenicity
    - Material Mediated Pyrogen

The Silk Road Access Catheter is considered to be an externally communicating medical device with circulating blood contact for less than 24 hours. Exceptions include the non-patient contacting components, which are assembled encapsulated with the blood-contacting layers of the catheter and include the catheter radiopaque marker band, catheter axial reinforcement members and adhesives.

Bench Testing

- Visual Inspection and Dimensional Verification
- Coating Particulate (USP 788)
- Coating Integrity
- Liquid Leakage (ISO 10555-1)

- Air Leakage (ISO 10555-1)
- Kink Resistance
- Torsion
- Guidewire Advancement and Withdrawal Force
- Burst
- Bending Stiffness Characterization
- Aspiration Rate Characterization
- Flush Rate Characterization
- Tensile Test (ISO 10555-1)
- Corrosion (ISO 10555-1)
- Radiopacity
- Simulated Preparation and Use
- Shelf Life

Animal Studies

A GLP animal study was previously performed to evaluate the safety, performance and handling of the Predicate Device in the canine model. Based on pathology and histopathology results, the safety acceptance criteria for the studies were met. Performance and handling observations were made based on detailed characteristics of the device. No untoward observations were found by the clinician. The *in vivo* performance testing of the Predicate Device Silk Road Access Catheter, demonstrating that the product is safe for its labeled indications, is applicable to the Subject Device because the basic design and fundamental technology is unchanged.

Clinical Performance Testing

The Predicate Device was cleared based on the results of only non-clinical testing, therefore, only non-clinical testing was required to support substantial equivalence.

VIII. CONCLUSIONS

The conclusions drawn from non-clinical tests demonstrate the Subject Device is substantially equivalent to the Predicate Device in its intended use.